Supreme Court, U.S.
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No. 02-

IN THE
# Supreme Court of the United States

DUKE UNIVERSITY,

*Petitioner,*

*v.*

JOHN M. J. MADEY,

*Respondent.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

## PETITION FOR A WRIT OF CERTIORARI

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135 pp

## QUESTION PRESENTED

Whether non-profit universities are precluded from asserting the experimental use exemption from liability for patent infringement merely because their research programs serve legitimate educational purposes.

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## OPINIONS BELOW

The opinion of the United States Court of Appeals for the Federal Circuit (App. A, *infra*, 1a to 30a), is reported at 307 F.3d 1351. Neither of the district court opinions (App. B & C, *infra*, 31a to 99a) is reported.

## STATEMENT OF JURISDICTION

The United States Court of Appeals for the Federal Circuit entered its judgment on October 3, 2002. This Court has jurisdiction over this petition pursuant to 28 U.S.C. § 1254(1).

## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves the proper interpretation of 35 U.S.C. § 271(a), which provides:

> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States during the term of the patent therefor, infringes the patent.

The statute was enacted pursuant to Article I, Section 8, Clause 8 of the United States Constitution, which provides:

> The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

## STATEMENT OF THE CASE

John M.J. Madey ("Dr. Madey"), a scientist and scholar in the field of electromagnetic radiation, invented the free electron laser ("FEL"). (App. A, *infra*, at 2a). Dr. Madey and his colleagues developed two inventions at issue in this case: a microwave electron gun, which is used as an electron source for the FEL and is the subject of U.S. Patent No. 4,641,103 ("the '103 patent"); and a "phase-locking" process and apparatus known as the "Free-Electron Laser Oscillator For Simultaneous Narrow Spectral Resolution and Fast Time Resolution Spectroscopy," which is the subject of U.S. Patent No. 5,130,994 ("the '994 patent"). (App. A, *infra*, at 3a-4a).

After conducting research at Stanford University, Dr. Madey left Stanford for Duke University ("Duke" or "the University") in 1989. (App. A, *infra*, at 2a). Duke built an FEL research lab to house FEL equipment, including the Mark III FEL, which had been transferred by the government and Stanford to Duke. (App. A, *infra*, at 2a). Dr. Madey served as director of the Duke FEL Lab for almost a decade. (App. A, *infra*, at 3a). Determining that Dr. Madey was not a competent manager, Duke removed him as director of the FEL Lab in 1997. Dr. Madey subsequently resigned from the University. (App. A, *infra*, at 3a).

After his removal as director, Dr. Madey sued Duke, alleging violations of the Age Discrimination in Employment Act of 1967 and the federal patent law, 35 U.S.C. § 271(a), in addition to various common-law claims. Dr. Madey invoked the district court's jurisdiction under 28 U.S.C. §§ 1331 and 1338(a), and alleged that Duke's use of two microwave electron guns in the Duke FEL Lab violated the '103 patent. (App. A, *infra*, at 3a). Approximately nine

months later, Dr. Madey filed an amended complaint, adding, among other things, an additional claim that Duke's use of the Mark III FEL in the Duke FEL Lab infringed the '994 patent. Madey also amended his original patent infringement claim to allege that Duke infringed the '103 patent through its use of a so-called Test Stand Gun.

Duke moved to dismiss the '103 patent claim with regard to the two guns in the Duke FEL Lab, arguing that the Court of Claims had exclusive subject matter jurisdiction over this claim. The district court granted the motion to the extent Duke's uses of the '103 patent were undertaken pursuant to a federal grant, ruling that the uses were essentially "by and for" the government within the meaning of 28 U.S.C. § 1498(a). (App. C, *infra*, at 66a-70a). The district court retained jurisdiction over the infringement claim to the extent it alleged use of the patent outside the scope of the federal grant. (App. C, *infra*, at 70a).

After substantial discovery, Duke moved for partial summary judgment on Dr. Madey's remaining patent infringement claims. (App. B, *infra*, at 31a-32a). Duke contended that it could not be held liable for any potential infringement of the '103 and '994 patents because "essentially all" of its research "was authorized by the Government, conducted for the Government, or funded by the Government." (App. B, *infra*, at 39a). Duke also argued that uses of the '103 and '994 patents were excepted from Section 271(a) liability pursuant to the "experimental use exception" because they were undertaken in pursuit of academic research with no commercial purpose. (App. B, *infra*, at 39a).[1]

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1. Duke filed a separate motion for partial summary judgment of non-infringement of the '103 patent with respect to the Test Stand (Cont'd)

The district court granted Duke's motion for partial summary judgment based on the experimental use exception and declined to exercise supplemental jurisdiction over the remaining state law claims. (App. B, *infra*, at 53a-54a).[2] The court determined that, "[a]lthough the scope of the defense has recently been the issue of much debate, to date, the experimental use defense remains viable and may be asserted in those cases in which the allegedly infringing use of the patent is made for experimental, non-profit purposes only." (App. B, *infra*, at 40a (citations omitted)). The district court concluded that the record supported Duke's contention that its "primary purpose is to teach, research, and expand knowledge, and not to engage in patent development for the purpose of commercial benefit." (App. B, *infra*, at 43a). The district court also concluded that "all of [Duke's] uses of the devices covered by the '103 and '994 Patents have been in furtherance of its educational purpose or for experimentation only." (App. B, *infra*, 44a, citations omitted). Accordingly, the district court held that the evidence could not support a jury verdict in Dr. Madey's favor. (App. B, *infra*, at 46a).

Dr. Madey appealed the district court's judgment, (App. A, *infra*, at 1a), and the United States Court of Appeals for the Federal Circuit reversed. The Federal Circuit first held that the district court erred in deciding that any uses of the patented FEL equipment falling within Duke's federal

(Cont'd)

Gun. The district court granted Duke's summary judgment motion, and the Federal Circuit affirmed this decision on appeal. (App. A, *infra*, at 27a-28a).

2. Dr. Madey's other claims arising under federal law had previously been dismissed pursuant to Fed. R. Civ. P. 12(b)(6). (App. C, *infra*, at 99a).

grant should be dismissed as uses "by and for the government." (App. A, *infra*, at 189). The court concluded that the district court failed to "clearly identify, discuss or analyze the particular statements or aspects of the [federal] grant that may have provided the government's authorization or consent to be sued[,]" (App. A, *infra*, at 18a), and remanded this aspect of the case to the district court to determine "which uses fall within the scope of the [federal] grant and which uses are outside that scope." (App. A, *infra*, at 20a).

The Federal Circuit also reversed the district court's decision granting summary judgment on Dr. Madey's patent infringement claims based on the experimental use exception. The Federal Circuit acknowledged that its precedent established that the user of a patented invention is not liable for infringement if the use is "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." (App. A, *infra*, at 26a). The court of appeals, however, viewed this "experimental use defense" as "very narrow and strictly limited" such that the 'slightest commercial implication'" destroys it. (App. A, *infra*, at 24a). The Federal Circuit then went further. It concluded that research institutions or entities engaging in wholly non-commercial endeavors were liable for patent infringement if their uses of patented inventions furthered their "legitimate business." (App. A, *infra*, at 26a). Since an academic research institution's "business" is experimentation, the Federal Circuit's formulation of the exception renders it an empty shell, unavailable to the very entities the exemption was intended to cover.

The Federal Circuit wrongly relied on *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976), which merely held, consistent with the explicit language of 28 U.S.C. § 1498, that a plaintiff has a remedy in the Court of Claims against

the United States for the infringing manufacture of goods for the United States if the goods were not manufactured for experimental purposes, even if the United States ultimately uses the goods for experimental purposes. *See* 547 F.2d at 1125-26. Misapplying language from *Pitcairn*, the court of appeals held that no "alleged infringer" of a patent may take advantage of the experimental use doctrine if its non-commercial use of a patented invention in any way furthers the "infringer's legitimate business." (App. A, *infra*, at 25a).

In reaching this conclusion, the Federal Circuit disapproved of *Ruth v. Stearns-Roger Mfg. Co.*, 12 F. Supp. 697 (D. Colo. 1935), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936), the only reported case addressing application of the experimental use exception to an academic institution's non-commercial use of a patented invention. (App. A, *infra*, at 25a). In *Ruth*, the district court held that "a manufacturer of equipment covered by patents was not liable for contributory infringement because the end-user purchaser was the Colorado School of Mines, which used the equipment in furtherance of its educational purpose." (App. A, *infra*, at 25a). The Federal Circuit concluded that *Ruth* was "inconsistent" with Federal Circuit precedent. (App. A, *infra*, at 25a).

In light of its legal conclusions, the Federal Circuit remanded the case to the district court to determine if Duke's use of the patented inventions furthered Duke's "legitimate business objectives, including educating and enlightening students and faculty" or "increas[ing] the status of the institution and lur[ing] lucrative research grants." (App. A, *infra*, at 25a).

## REASONS FOR GRANTING THE PETITION

Supreme Court review is necessary because the Federal Circuit's decision, which effectively is the law of the land, disrupts a delicate balance in the patent law, contrary to the legislative judgment of Congress and the "settled expectations of the inventing community." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 1841 (2002) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997)). The centuries-old experimental use exception to patent infringement diffuses the inherent tension between encouraging invention through limited monopoly and furthering innovation and science by providing the public with access to knowledge.

Congress implicitly embraced the exception when recodifying the patent laws in 1952. The Federal Circuit Court's decision, however, overrules Congress' legislative judgment and creates an untenable paradox: non-profit research institutions are now precluded from making experimental use of patents to further knowledge and research while avowedly commercial enterprises may still take advantage of the exception.

The Federal Circuit's decision has monumental consequences for scientific research in this country. Much scientific research involves a multitude of patents or a single patent that is the keystone to all further research in a particular area. Until now, scientists at non-profit universities and research institutions have assumed that their research does not implicate patent law so long as it serves no immediate commercial purpose. This assumption has allowed critical non-profit research in fields such as molecular biology and biotechnology to move forward without the prohibitive

costs, substantial delays, or complete roadblocks that might otherwise be associated with multiple patents, exclusive licensing rights, or an uncooperative patent holder. The Federal Circuit's decision brings the science community's long-standing course of conduct into serious question and jeopardizes the framework under which much non-profit research is conducted. By explicitly eliminating the experimental use exception for research institutions, the Federal Circuit's opinion undoubtedly will have a significant chilling effect on research at major universities and other non-profit research institutions.

## I.

## THE FEDERAL CIRCUIT'S DECISION, WHICH NOW STANDS AS THE LAW OF THE LAND, UNCAUTIOUSLY DISRUPTS BOTH THE DELICATE PATENT LAW BALANCE EMBRACED BY CONGRESS AND THE SETTLED EXPECTATIONS OF THE INVENTING COMMUNITY

The United States Constitution allows Congress to grant inventors exclusive rights to their inventions for a limited time in order to "promote the Progress of Science." U.S. Const. art. I, § 9, cl. 8. Such exclusive rights may motivate invention but also may act as a barrier to future inventions. *See* Lauren C. Bruzzone, *The Research Exemption: A Proposal*, 21 AIPLA Q. J. 52, 53 (1993). Consequently, "[f]rom their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself. . . ." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

The experimental use exception, which has been in existence since the early nineteenth century, forms part of this balance. Justice Story first alluded to the exception in 1813 while sitting on the Massachusetts Circuit Court in *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600). In *Whittemore*, the defendant challenged a jury instruction that "the making of a machine fit for use, and with a design to use it for profit, was an infringement of the [plaintiff's] patent right." 29 F. Cas. at 1121. Justice Story upheld the instruction in its entirety, noting that it was "certainly favorable to the defendant." *Id.* Justice Story observed that "it could never have been the intention of the legislature to punish a man, who constructed . . . a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." *Id.*

Justice Story gave more explicit content to the "experimental use exception" in *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391). In holding that a sheriff could not be liable for patent infringement for seizing and selling materials forming a patented machine, Justice Story noted that "the making of a patented machine to be an offence within the purview of [the patent laws] must be the making ***with an intent to use for profit***, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification." 21 F. Cas. at 555 (emphasis added).

By the end of the century, the experimental use exception was well entrenched in the common law. In *Poppenhusen v. Falke*, 19 F. Cas. 1048 (C.C.S.D.N.Y. 1861) (No. 11,279), for example, the court considered it "well settled" that "an experiment with a patented article for the sole purpose

of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee." 19 F. Cas. at 1049. And, in 1890, the experimental use exception was summarized in a leading treatise, *The Law of Patents for Useful Inventions*, by William C. Robinson. Robinson's treatise explicitly recognized that the use of a patent that "produce[d] no pecuniary result" was not a violation of the patent laws:

> § 898. No Act an Infringement unless it Affects the Pecuniary Interests of the Owner of the Patented Invention.
>
> Moreover, the interest to be promoted by the wrongful employment of the invention must be hostile to the interest of the patentee. The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. These, though not always taking the shape of money, are of a pecuniary character, and their value is capable of estimation like other property. Hence acts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one. An unauthorized sale of the invention is always such an act. But the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. Thus where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized,

> the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind. . . .

3 William C. Robinson, *The Law of Patents for Useful Inventions* 55-56 (photo. reprint 1972) (1890) (footnote omitted).

By the middle of the twentieth century, courts had fully accepted the dichotomy between commercial and non-commercial uses of a patent, consistently holding that experimental use of a patent for non-commercial purposes did not constitute infringement under the patent laws. *See, e.g., Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223, 229 (S.D.N.Y. 1944) (excepting from patent infringement those devices manufactured by the defendant which were neither manufactured for sale nor sold but were "built . . . only experimentally"), *aff'd*, 156 F.2d 29 (2d Cir. 1946); *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305, 333 (N.D.W. Va. 1937) (citations omitted) (holding that experimental testing of plaintiff's patented device before using a different variation of the device in defendant's machine "was not in law an act of infringement as [the patented device] was not commercially sold"); *Ordinance Eng'g Corp. v. United States*, 84 Ct. Cl. 1, 2, 4 (1936) (sustaining plaintiff's infringement claims against the government for manufacturing patented service shells but excepting from plaintiff's claim any ballistic or experimental shells manufactured by the government for testing and experimental use only); *cf. United States Mitis Co. v. Carnegie Steel Co.*, 89 F. 343, 351 (C.C.W.D. Pa. 1898) (defendant could not invoke the experimental use defense where the use of plaintiff's patent was "in the course of business and for profit"), *aff'd*, 90 F. 829 (3d Cir. 1898);

*Bonsack Mach. Co. v. Underwood*, 73 F. 206, 211 (C.C.E.D.N.C. 1896) (same). More specifically, case law established that a research institution did not infringe a patent if it used a patented invention for experimental purposes only. *See Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 703 (D. Colo. 1935) (holding that because the "sale of parts [to the Colorado School of Mines] . . . were for use in laboratory machines used for experimental purposes," the sales "did not contribute to an infringing use"), *rev'd on other grounds*, 87 F.2d 35 (10th Cir. 1936).

This was the state of the law confronting Congress when it recodified the federal patent statute in 1952. Although Congress explicitly overruled certain judicial precedent with new statutory provisions, *see* 1 Donald S. Chisum, *Overview: Historical Development of Patent Law*, *in* Chisum on Patents OV-12 to 13 (2002), it did nothing to overrule case law on the scope of liability for the direct infringement of a patent. Congress added Section 271(a), which generally defines an infringer as one who "without authority makes, uses or sells any patented invention." 35 U.S.C. § 271(a). But Section 271(a), like most of the 1952 Patent Act, was added only as a declaration of already-established law. *See* 35 U.S.C.A. § 271, Rev. Notes and Leg. Rprts. (2001) (discussing 1952 Acts, and explaining that "[t]he first paragraph of [section 271] is declaratory only"); Chisum, *supra*, at OV-12 ("To a large extent, the 1952 Act rearranged existing statutory provisions and stated in statutory forms matters previously recognized only in court decisions and Patent Office practice . . . ."). Indeed, the Court has already acknowledged that Section 271(a) "left intact the entire body of case law on direct infringement." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 342 (1961). In enacting the 1952 Patent Act without eliminating the experimental use exception, Congress "is presumed to [have been] aware of

. . . [the] judicial interpretation of [the] statute and to [have] adopt[ed] that interpretation." *Lorillard v. Pons*, 434 U.S. 575, 580 (1978).

In this case, the Federal Circuit overrode Congress' legislative judgment. It effectively eliminated the experimental use exception for research institutions by misapplying language from a wholly irrelevant case, *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976). *Pitcairn* stands for the unremarkable proposition that, under 28 U.S.C. § 1498, a plaintiff can recover compensation against the government in the Court of Claims for the infringing manufacture of goods for the United States where the goods are not manufactured for experimental purposes, even if the goods ultimately are used by the government for experimental purposes. *See* 547 F.2d at 1125-26. This result follows ineluctably from the disjunctive language of 28 U.S.C. § 1498(a), which provides that a plaintiff's remedy is against the United States in the Court of Claims "[w]henever an invention described in and covered by a patent of the United States is used ***or*** manufactured by or for the United States without license of the owner thereof." 28 U.S.C. § 1498(a) (emphasis added). In explaining that the products were not manufactured ***for*** experimental use, the court mentioned that testing by the government of items manufactured for it is "in keeping with the legitimate business of the using agency." *Pitcairn*, 547 F.2d at 1125-26. In other words, according to the *Pitcairn* court, the fact that the government normally tests products manufactured for it does not mean that the products are manufactured for experimental use.

Seizing on *Pitcairn's* "legitimate business" language and applying it out of context, the Federal Circuit in this case fashioned a very different rule of law: an institution may not

take advantage of the experimental use exception if its non-commercial use of a patented invention in any way furthers the "infringer's legitimate business." (App. A, *infra*, at 26a). This standard seals the coffin on the experimental use exception for private universities. No research institution will be able to demonstrate that its experimental use of any patent fails to further the institution's "legitimate business." Because such entities are "in the business" of research and education, they can never use a patent experimentally without implicating their "business" objectives, even when such objectives have absolutely no commercial elements. The Federal Circuit, moreover, has declared that a university infringes a patent when it uses a patented invention for non-commercial experimental purposes even if such use only ***indirectly*** furthers the university's interests. According to the Federal Circuit, a university's use of a patent which might arguably help to "increase [its] status" or its ability to "lure" students, faculty and grant money is a use now subject to the full proscriptive force of the patent laws. (App. A, *infra*, at 25a).

The Federal Circuit's decision thereby turns the experimental use exception on its head. To the extent the exception retains any vitality, it is available only to individuals or commercial entities not in the "business" of research or education.[3] There is no principled basis for

3. It is questionable whether the experimental use exception has any content at all after the Federal Circuit's opinion. Not only are research institutions precluded from using the defense based on the "legitimate business test," but no entity may successfully rely on the defense if its experimental use of a patent "has the slightest commercial implication." (App. A, *infra*, at 24a). Depending on the court's interpretation of "slight commercial implication," the opinion could well be the death knell for the nearly two-hundred-year-old doctrine.

subjecting non-profit research institutions to patent infringement claims for their non-commercial use of patents while allowing other private entities this safe haven. To the contrary, all policy considerations favor allowing the exception for non-profit entities seeking to advance education and knowledge.[4]

The Federal Circuit is the only court now authorized to hear patent appeals. *See* H.R. 312, 97th Cong. 20-22 (1981). Its opinions therefore create "national law precedent." *Id.* In light of this reality, the Court recently admonished the Federal Circuit to "be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo*, 122 S. Ct. at 1841 (citation omitted). The court of appeals wholly ignored the Court's admonition in this case. Its opinion is manifestly erroneous and cannot be squared with case law as it existed in 1952 and as implicitly incorporated into the 1952 Patent Act.

The "interlocutory" nature of the Federal Circuit's decision does not counsel against review. Although the Federal Circuit remanded the case to the district court to determine if Duke's use of Dr. Madey's patents furthered its "legitimate business objectives," (App. A, *infra*, at 26a), the district court's role on remand is purely perfunctory.

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4. The Federal Circuit's opinion only broadens the inconsistencies that already exist in this area of the law. Pursuant to *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Savings Bank*, 527 U.S. 627 (1999), a public research institution whose research qualifies as "state action" may experiment with a patented invention without any liability in damages, even if the purpose of the experiment is manifestly commercial in nature. *See* 527 U.S. at 647-48. This result now stands in stark contrast to the complete abrogation of patent infringement protection for private universities.

Given the Federal Circuit's standard for deciding whether the university's use furthered its legitimate business objectives, the district court can reach only one result. In the meantime, the decision stands as the law of the land. The Court should review this case to make clear — consistent with long-settled expectations of the scientific community — that non-profit research institutions may make experimental use of patented inventions without running afoul of the patent law.

## II.

## THE FEDERAL CIRCUIT'S OPINION PRESENTS AN ISSUE OF GREAT NATIONAL IMPORTANCE

The Federal Circuit's opinion will have dire consequences for non-profit research institutions and for the future health of our Nation. The importance to our society of scientific research conducted at universities and other non-profit research institutions is incalculable. Many of the building blocks to this research, however, are patented. The Federal Circuit's decision threatens to delay or stymie research based on such patented inventions.

The scientific contributions of those engaged in "philosophical inquiry" cannot be exaggerated. Universities and other non-profit research institutions often seek to further knowledge and innovation — not for profit — but for the greater common good. *See* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 Yale L.J. 177, 181-82 (1987) (hereinafter Eisenberg, *Proprietary Rights*); Eyal H. Barash, Comment, *Experimental Uses, Patents, and Scientific Progress*, 91 Nw. U. L. Rev. 667, 703 (1997). In recognition of this important endeavor,

the government spends billions of dollars each year funding non-commercial research at universities. *See* Suzanne T. Michel, Comment, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7:2 High Tech. L.J. 369, 401 (1993). Indeed, NIH is by far the largest funding source for university-based research in the life sciences. *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law & Contemp. Probs. 1, 35 n.109 (2002) (unpublished master copy), *available at* http://www.law.upenn.edu/fac/akrai/lcp.update.922.doc (last visited Dec. 20, 2002) (hereinafter Rai & Eisenberg, *Progress of Biomedicine*). It is no coincidence that 56 "of the 75 American Nobel laureates in physiology or medicine in the period from 1945-1998, . . . ha[ve] either worked at NIH or were supported by NIH prior to winning the prize." *Id.* (citation omitted).

One of the fundamental functions of non-commercial research is to verify and replicate the results of prior research. *See* Ned A. Israelsen, *Making, Using, and Selling Without Infringing: An Examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AIPLA Q. J., 457, 470-71 (1989); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017, 1048-55 (1989) (hereinafter Eisenberg, *Patents and the Progress of Science*). It is only through this peer review that scientific theories and discoveries gain credibility and vitality. *See id.*

Patents, however, now permeate many critical areas of scientific research. For instance, "[s]ome of the most important research tools in biotechnology [are] subject to proprietary restraints." Janice Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for*

*Biomedical Research Tools*, 76 Was. L. Rev. 1, 12 (2001). These patented inventions and processes include the technology used to create a "cre-loxP mouse," a mouse in which "a targeted gene is deleted when the cre gene encounters two loxP DNA segments bracketing the targeted gene;" the "Cohen-Boyer" method for gene cloning; the "oncomouse," which is a tumor-prone mouse useful as a model in cancer research; and human embryonic stem cells, "from which any type of human tissue can be grown." *Id.* at 12-14.

Not only are some of the basic building blocks to much of biotech research patented, but the increased tendency to patent innovation in this field has resulted in "a spiral of overlapping patent claims in the hands of different owners." Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698, 698 (1998) (hereinafter Heller & Eisenberg, *Anticommons*). This "proliferation of intellectual property rights" now allows each individual patent holder "to set up another tollbooth" delaying or even blocking further research innovation. *Id.* at 698-99.

Academic researchers did not face such "toll-booths" prior to the Federal Circuit's opinion in this case, largely because the universal assumption among universities and academic researchers was that the experimental use exception permitted non-profit researchers to conduct non-commercial experiments without regard to possible patent infringement. *See, e.g.*, John P. Walsh et al., *Research Tool Patenting and Licensing and Biomedical Innovation* 44 (Dec. 11, 2002) (unpublished draft on file with Petitioner); Rubenstein,

*Promega Wins Round in European Patent Office*, Legal Times, Aug. 2001, at 26; *see also* Barash, *supra*, at 697-99 (in general, scientists at non-profit institutions conduct research without engaging in patent background checks). The assumption that the experimental use exception protected universities engaging in non-commercial research from patent infringement claims was shared by legal commentators and even by some license holders. *See* Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. Pat. and Trademark Off. Soc'y 617, 633 (1985) ("Few would deny the experimental use exception for research on patented technology performed at a university in furtherance of its educational function."); Walsh, *supra*, at 44.

By eliminating the long-standing experimental use exception for universities and other non-profit research institutions, the Federal Circuit's opinion threatens substantial delay, further commercialization of non-profit research, and even the complete cessation of certain research projects. *See, e.g.*, Mueller, *supra*, at 7 ("[T]he stacking of intellectual property obligations as successive tools used in the course of an extended research project has the potential to impede or even preclude the development of new and better diagnostic and therapeutic products.") (citation omitted). As one commentator has noted, "'it is ludicrous to expect every researcher to obtain a license in advance of conducting a simple experiment, each time he sees a newly issued patent and attempts to duplicate the efforts in his laboratory.'" Barash, *supra*, at 698-99 (citation omitted). The Federal Circuit's opinion, however, may now require non-profit researchers to do just that. The failure to obtain permission to use patented materials may now result in pervasive and

costly litigation. *See* Rai & Eisenberg, *Progress of Biomedicine*, *supra*, at 14 n.45. As more and more patent holders begin to realize that they can extract high payment from universities or otherwise exploit non-profit innovations, the number of patent holders asserting rights against universities can be expected to rise dramatically.

The possibility that the patent system could stifle or even stymie the progress of biotechnology and other important fields of research is both real and profound. For instance, even if a university were willing to undertake an onerous background check of potential patents for its non-commercial experimentation, there may be so many patents underlying a contemplated research project that obtaining the necessary licenses becomes difficult or even impossible. *See* Heller & Eisenberg, *Anticommons*, *supra*, at 699-700. The transaction costs of obtaining these multiple licenses also may be prohibitively high. *See id.* at 700. In addition, a researcher may discover that one of the materials necessary for a contemplated research project is covered by a patent which has been exclusively licensed to another entity. *See id.* Such a scenario is not out of the question, even with respect to a fundamental research innovation. For example, human embryonic stem cells were recently patented by the Wisconsin Alumni Research Foundation ("WARF"). WARF then granted an exclusive license to use the cells to a commercial entity for commercial use. *See* Mueller, *supra*, at 14. Only after significant media attention did WARF reconsider its position and repudiate the license for three of the six cells. *See* Rai & Eisenberg, *Progress of Biomedicine*, *supra*, at 19 n.59. Without an experimental use exception, the existence of an

exclusive license would stop in its tracks any research conducted by a non-licensee.

An additional host of problems are certain to arise based on the inherent difficulty for researchers in identifying all patents potentially implicated by the course of their studies. Researchers are not always aware of the path their research might take and what materials may be necessary to continue with a particular line of inquiry. "Interrupting an ongoing research project to obtain a license to use a prior discovery that has unexpectedly proved relevant to the inquiry could cause wasteful delays." Eisenberg, *Patents and the Progress of Science*, *supra*, at 1056. Even worse, a discovery mid-stream that a requisite patented process has been exclusively licensed could bring a research project to a grinding halt.

The uncooperative patent holder who demands unreasonable returns in exchange for the right to use a particular patent is now also a significant threat. *See* Heller & Eisenberg, *Anticommons*, *supra*, at 699-701. The terms of a license may be unreasonable because the patent holder overvalues his patent or because the proposed terms unduly restrict the researcher's future actions. *See id.* at 701. Indeed, NIH strongly discourages researchers who use NIH funds from agreeing to reach-through royalty arrangements because they tend to hinder, rather than promote, the dissemination of scientific knowledge. *See* Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,091, 72,093 (Dec. 23, 1999). The patent holder might also torpedo a non-profit research project through destructive negotiation tactics. *See* Heller & Eisenberg, *Anticommons*, *supra*, at 701.

For instance, in order to gain information about another researcher's project within the patent holder's field, the patent holder might demand that a researcher divulge confidential information about the contemplated project. A researcher, however, may rather forego a project than reveal too many of his original ideas to a potential rival. *See* Eisenberg, *Patents and the Progress of Science*, *supra*, at 1061-63.

Indeed, Dr. Madey's actions in this case demonstrate a university's vulnerability to the random whims of a patent holder. Dr. Madey allowed Duke to use his patents for years. Only when he became disgruntled with the University's decisions regarding leadership in the laboratory did he seek to enforce his alleged patent rights against Duke. (App. B, *infra*, at 35a-37a). If Dr. Madey prevails in this case, it will signal to other disgruntled patent holders as well as patent holders who do not agree with particular hypotheses or lines of research that they may effectively prevent others from undertaking contested research. *See* Eisenberg, *Patents and the Progress of Science*, *supra*, at 1054-55.

It is no comfort that, until now, most patent holders have failed to assert their patent rights against the non-profit research community. *See generally* David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 Hous. J. Int'l L. 615, 659 (1994); Hantman, *supra*, at 642. The dearth of lawsuits can be attributed, at least in part, to the recognized existence of the experimental use exception and the assumption within the science community that non-profit research enjoyed an exemption from patent infringement claims. *See id.* Moreover, even a single patent holder can significantly impede scientific progress. For instance, in 1991, Hoffman-La Roche (Roche) obtained patent rights to a thermostable enzyme Thermus aquaticus

YT1 DNA polymerase (Taq), which is a basic and widely used biotechnology tool for DNA sequencing, as well as rights to "the revolutionary DNA amplification process [utilizing] Taq." Mueller, *supra*, at 3. In accusing another company of selling Taq outside the license Roche sold to it, Roche "accused more than forty U.S. universities and research institutions (including Harvard, Stanford, Massachusetts Institute of Technology, the Salk Institute, the Scripps Research Institute, and the National Cancer Institute) and more than 200 individual scientists of infringing these patents." *Id.* While Roche never formally joined any of the research institutions or individual scientists in the lawsuit, its accusations "sent a chill through the research community." Rubenstein, *supra*, at 26. Now that the Federal Circuit has proclaimed the experimental use exception unavailable to research institutions, companies like Roche may be more likely to bring patent infringement claims against non-profit research institutions or their individual scientists. *See* Mueller, *supra*, at 3 (noting that Roche spokesperson warned that she "wouldn't want to predict" what future patent enforcement actions Roche might take against the scientific community).

Equally unsatisfying is the argument that patent holders will not aggressively assert their patent rights against universities because it is unpopular to do so, *see generally* Walsh et al., *supra*, at 45-46; Parker, *supra*, at 658-59, or because any potential damage from the non-commercial use of a patent is small, *see* Hantman, *supra*, at 642. Relying on the good will of the patent holder will not provide non-profit research institutions with the security or protection they need to go forward with lengthy and ground-breaking research projects. If universities are subject to liability for patent infringement when using a patent experimentally,

any holder of a patent on an important innovation might be able, at any time, to enjoin a university from using the patent; seek restrictive royalty reach-through agreements; or charge extremely high fees for licenses or other agreements. *See* Eisenberg, *Proprietary Rights*, *supra*, at 217-18; Heller & Eisenberg, *Anticommons*, *supra*, at 699-701. The threat of any of these actions can stifle the scope and creativity of a research project or — even worse — cause the project to be aborted altogether. This case provides a prime example of this potential danger. Dr. Madey asserted his patent rights against Duke only after employment disputes arose between him and the University. (App. B, *infra*, at 35a-37a). In addition, as patentees realize that universities are subject to patent infringement claims for any experimental use of a patent, they will undoubtedly seek to enforce their patent rights against such institutions.

Finally, the importance of having an experimental use exception remains, despite arguments that many infringing activities in laboratories are too isolated and innocuous to attract the attention of a patent holder. *See generally* Michelle Walters, *De Minimis Use and Experimental Use Exceptions to Patent Infringement: A Comment on the* Embrex *Concurrence*, 29 AIPLA Q. J. 509, 539 (2001). It is no solution to the dilemma presented by the elimination of the experimental use exception to expect the scientific community simply to violate the law. *See* Rai & Eisenberg, *Progress of Biomedicine*, *supra*, at 14 n.45 (noting that "one might question the long-term viability of a solution that is based on pervasive law-breaking that may yet trigger costly litigation when it comes to light"). Universities are not scofflaws, and they cannot be expected to advise students and faculty to violate the law.

Scientific progress is essential to the health of our Nation. The very fabric of scientific method depends on the ability of scientists to build upon the discoveries of those who have gone before them. *See* Eisenberg, *Patents and the Progress of Science*, *supra*, at 1055-60. As Sir Isaac Newton famously proclaimed, "If I have seen further, it is by standing on the shoulders of giants." *Id.* at 1055. Thus, universities and other non-profit institutions must be able to access prior information in their fields to further knowledge and promote science.

Until the Federal Circuit's opinion in this case, "[t]he experimental use doctrine offer[ed] a potential mechanism for reconciling the patent monopoly with the interest of the research community . . . ." Eisenberg, *Proprietary Rights*, *supra*, at 230. Without the exception, patent law is certain to have a substantial chilling effect on the course of future non-profit research. The Court should review this case to restore the experimental use exception for non-profit research institutions, thereby allowing researchers safely to conduct important and potentially life-saving research.

## CONCLUSION

The Court should grant the petition for writ of certiorari to the United States Court of Appeals for the Federal Circuit.

Respectfully Submitted,

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